



Public Health

Seattle & King County

HEALTHY PEOPLE. HEALTHY COMMUNITIES.

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HIV Incidence Projects - Information for Jail Health Clinic Clients

Susan Buskin (206 205-6123) and Gary Goldbaum (206 296-4991)

Background and Purpose:

We are doing a study of the serologic testing algorithm for recent HIV seroconversion (STARHS). STARHS uses results from the standard HIV test and results from another HIV test to estimate recent infection. We are asking you to be part of our research because you had a positive HIV antibody test. Public Health - Seattle & King County (PHSKC) is working with the Centers for Disease Control and Prevention (CDC) on this study. **We don't know how accurate STARHS is.** The STARHS method was developed to look at HIV infection in *groups* of people, not individuals. Group results will tell us what percent of people in the group **may** have been recently infected with HIV.

STARHS uses the same blood taken for HIV testing. No more blood needs to be taken. This HIV test is not approved by the Food and Drug Administration (FDA). **This study is part of an Investigational New Drug (IND) application because the STARHS is different from the usual HIV test. The FDA oversees research of new tests under an IND.**

Procedures:

If you agree to be in this research, this is what happens:

1. You tell the testing counselor that you want to be part of the study.
2. No blood will be drawn. Blood left over from your HIV test will be used.

3. Although we don't know how accurate STARHS is, you can still receive your test result. You don't have to get your result if you don't want to.

We will also combine results from STARHS with information from your HIV counseling session (your age, sex, race, risk factors for HIV, and whether you are taking medicine for HIV) to learn more about HIV in King County.

If you have tested for HIV confidentially, we will combine results from STARHS with information from your HIV/AIDS case report (date of first positive HIV test, history of treatment for HIV, and risks for HIV). Results from STARHS will be included in your HIV/AIDS case report and sent to the CDC without your name.

Risks/Discomfort:

1. **Your STARHS result may not be accurate.** Studies suggest that STARHS **may** identify most people who were infected with HIV within the past year. **Your HIV-antibody test result won't change, even if STARHS may not be accurate.**
2. You may feel upset or uncomfortable thinking you may have been infected with HIV in the past year. You may think certain recent partners gave you HIV. The HIV testing counselor is available to talk about your concerns, if you wish.

HIV Incidence Projects - Prevention Division

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City of Seattle

Gregory J. Nickels, Mayor



King County

Ron Sims, Executive

3. There is a very small chance that results from STARHS could become known to someone outside of the research staff. We will make every effort to prevent this and will protect your privacy.

Benefits:

1. Taking part in the study may not benefit you directly.
2. We will refer you to other HIV-related services if you wish.
3. STARHS, along with other information you provide, may help you and your counselor or health care provider decide which sexual or needle-sharing partners need to be told that they may have been exposed to HIV.
4. This research will help us understand what is going on with the HIV epidemic. We can then make decisions about the best ways to prevent new infections.

Your Rights:

You don't have to take part in this research. If you choose to take part, you may withdraw at any time. You won't be denied any services if you decide not to participate. You can still take part in the counseling sessions. If you agree to let us test your blood, you don't have to get your STARHS result. Your participation in this study will not change your release date from jail or prison.

Protecting Your Privacy:

We will record the STARHS result in our secure, password-protected computers. Your STARHS result will also be put in HIV testing and HIV/AIDS case records at Public Health-Seattle & King County. If you wish to learn your STARHS result in the future, your name or an anonymous code may be used to find your result at the site of your HIV test.

State laws protect the privacy of medical records and HIV testing. We will keep your test results confidential and secure. We won't give the results of your STARHS or HIV tests to anybody without your written permission. Only selected people working with HIV case records or on this and a related study in the same office at PHSKC will look at your STARHS result. The other study is looking at people who are recently diagnosed with HIV to find out if they have a type of HIV that resists medicines against the infection. All PHSKC researchers will protect the privacy of your result and will **only** use the information for research. All study files will be kept locked. All computers used for both projects are protected by passwords. All staff of PHSKC studies have signed an oath to protect confidentiality.

STARHS uses a blood test that hasn't been approved by the FDA for clinical use. The FDA has the right to look at clinical records of people who take part in research to make sure that proper procedures were followed.

Questions or Complaints:

If you have questions about this study at any time, you can talk to your HIV testing counselor. You may also call the researchers: Susan Buskin (206) 205-6123 or Gary Goldbaum (206) 296-4991. If you have questions about your rights as a participant, you may call Maggie Frederick at 1 (800) 583-8488. She works for the Washington State Institutional Review Board. The Board works to protect the rights of people who take part in studies.

This information sheet is yours to keep